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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,455	04/09/2004	Roger Akers	SYNT-P006US	1352
7590 02/14/2006 Elizabeth R. Hall & Associates, P.C. 1722 Maryland Street Houston, TX 77006-1718			EXAMINER BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	
DATE MAILED: 02/14/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/821,455

Applicant(s)

AKERS ET AL.

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 14 as amended recites that the second culture compartment of the claimed system includes both “a membrane carrier” with a membrane and “an outlet filter”. The originally filed disclosure does not provide support for this newly recited claim limitation.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Masahide et al.(JP 06-134210).

With respect to claim 1, the reference of Masahide et al. discloses a device (See Figures 1 and 2) that includes a fluid inlet (1); a first tubular housing (3) of fluid-impermeable material defining a compartment that is capable of supporting cells for culture; a first end piece (17); a second tubular housing (4) of fluid-impermeable material defining a compartment that is capable of supporting cells for culture; a fluid connector (16) connecting tubular housing (3 and 4), the fluid connector (16) includes a bore passing from the first side to the second side (See Figure 2); a connector filter (12) (See Figure 12 and 13 and paragraph [0013] of the English language machine translation) is mounted in housing (3) and is mounted to the fluid connector (16) and is positioned to filter a fluid stream passing from the first compartment to the second compartment; a fluid outlet (2); a distal end piece (17) connected to the fluid outlet; and an outlet filter (12) (See Figure 12 and 13 and paragraph [0013] of the English language machine translation) is mounted in housing (4) and is mounted to the fluid connector (17).

With respect to claim 2, the connector filter (12) positioned in housing (3) extends between the first end piece (17) and the fluid connector (16).

With respect to claim 3, the outlet filter (12) positioned in housing (4) extends between the distal end piece (17) and the fluid connector (16).

With respect to claim 4, the connector filter is a molecular weight cut-off filter.

With respect to claims 7, 8 and 9, the housings (3 and 4) include a penetration port, gas vent or fill means (10).

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 6 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masahide et al.(JP 06-134210).

The reference of Masahide et al. has been discussed above.

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With respect to claim 6, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide a fluid take-off in communication with the fluid connector bore for the known and expected result of providing a means to remove treated fluid before passing into the second chamber for sample analysis.

With respect to claim 10, rotation of the assembly with a drive assembly would have been obvious for the known and expected result of ensuring uniform distribution of the fluid stream and its components within the tubular housings.

With respect to claim 11, whether the two chambers are of the same or different volume would have been well within the purview of one having ordinary skill in the art based merely on the desired properties of the treatment system.

With respect to claims 12 and 13, the use of identifiers, such as bar codes, would have been obvious for the known and expected result of facilitating inventory of the components of the system using a bar code reader.

9. Claims 5 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masahide et al.(JP 06-134210) in view of Schwarz et al.(US 5,026,650).

The reference of Masahide et al. has been discussed above.

While the reference of Masahide et al. discloses the use of a plurality of tubular membranes (24), the above claims differ by reciting that the membrane includes a membrane support.

The reference of Schwarz et al. discloses that it is known in the art to provide a tubular membrane (40) provided on a membrane support (32).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a membrane support based merely on the size of the treatment system while ensuring structural integrity with respect to the membrane when traversing a long chamber.

### ***Response to Arguments***

10. Applicant's arguments, see pages 7-12, filed 11/14/05, with respect to the rejection(s) of claim(s) 1-19 under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the reference of Masahide et al.(JP 06-134210).


### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
William H. Boisner  
Primary Examiner  
Art Unit 1744

WHB